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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/645,594	08/25/00	KING	11157-14

001059
BERESKIN AND FARR
SCOTIA PLAZA
40 KING STREET WEST-SUITE 4000 BOX 401
TORONTO ON M5H 3Y2
CANADA

HM12/0606

AIR MAIL

EXAMINER

WELLS, L

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

06/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/645,594

Applicant(s)

KING, MALCOLM

Examiner

Lauren Q Wells

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not state whether the inventor is a sole or joint inventor of the invention claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 7-10, 12-18, 20, -22, 34-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5-7, 9-10, 12-21 of copending Application No. 09052614. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn towards analogous methods of improving mucus clearance comprising administering an effective amount of dextran.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "decreasing" in claims 1 and 20 and the term "improving" in claim 7 are relative terms which render the claims indefinite. The terms "decreasing" and "improving" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Speert et al. (5,514,665).

Art Unit: 1619

Speert et al. a method of preventing or reducing the risk of infection by bacterial pathogens in vivo by administering compositions of dextran or dextran sulphate. Disclosed is the effect of dextran sulphate on the adhesion of *P. aeruginosa*, an infection commonly manifested in cystic fibrosis patients, to buccal epithelial cells. Topical administration and aerosol administration of dextran sulphate is disclosed. The molecular weight of the dextran is disclosed as ranging between 3,000-1,000,000. Further disclosed are pharmaceutical carriers and concentrations of dextran sulfate in composition. See Col. 1, line 20-Col. 12, line 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7-10, 12-18, 20, -22, 34-27 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09052614 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application. Both sets of claims are drawn towards analogous methods of improving mucus clearance comprising administering an effective amount of dextran.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date

Art Unit: 1619

of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speert et al. (5,514,665) in view of Ahmed (5,980,865) and King et al.

Speert et al. fails to teach a method of clearing mucus, methods of diagnosing, and methods of determining dosage (see above discussion).

King et al. teach mucociliary clearance increase due to low-molecular weight heparin. It is disclosed that low molecular weight heparin treatment significantly reduced the viscoelasticity and spinnability of human CF sputum and healthy dog mucus. See entire disclosure.

Ahmed teaches a method of treating a mammalian patient suffering from allergic reactions, airway hyperresponsiveness, or inflammatory reactions comprising administering a pharmaceutical composition containing 0.005 to 1 mg/kg of ultra low molecular weight heparins or other sulfated polysaccharides having average molecular weights of about 1,000-3,000. Disclosed forms include topical and aerosol compositions. See Col. 2, line 49-Col. 4, line 34; Col. 8, line 20-Col. 12, line 67; Col. 17, line 36-Col. 20, line 8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the invention of Speert et al. with the teachings of Ahmed and King et al. and obtain a method for treating mucus clearance because a) Speert et al., Ahmed, and

Art Unit: 1619

King et al. all teach compositions for the alleviation of respiratory disorders; b) Speert et al. Ahmed, and King et al. all teach sulphated polysaccharides as active agents; c) Speert et al. and King et al. teach sulphated polysaccharides as treatments for cystic fibrosis; d) Ahmed teaches sulphated polysaccharides with similar molecular weights and forms as those disclosed in Speert et al. and Ahmed et al., as significantly reducing the viscoelasticity and spinnability of sputum and mucus.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
May 17, 2001


DAMERON L. JONES
PRIMARY EXAMINER